



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 21-02 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT AND THE SECRETARY'S DECLARATION UNDER THE ACT JANUARY 12, 2021

This Advisory Opinion responds to requests received by the Office of the General Counsel to clarify the meaning of the requirement, in certain PREP Act issuances (also known as “PREP Act Authorizations,” as referenced in n. 1, *infra*), that a COVID-19 vaccination “must be ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s).”¹ Some have raised concerns that satisfying the Advisory Committee on Immunization Practices’ (ACIP) allocation recommendations is a precondition to PREP Act coverage. It is not.

I. ANALYSIS

As used in the PREP Act Authorizations, the phrase, “must be ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s),” means that the vaccine must be one that ACIP recommends for the prevention of COVID-19; it does not mean that the vaccine be administered pursuant to any particular allocation guidance or recommendation.² This is clear when one reads these authorizations in context. The Secretary’s Third Amendment to his PREP Act Declaration (“Third Amendment”) authorized certain pharmacists and pharmacy interns to administer childhood vaccines. A requirement to do so, however, was that the vaccination “must be ordered and administered according to ACIP’s standard immunization schedule.”³ ACIP develops recommendations for which age groups should receive particular vaccines.⁴ Thus, when the Third Amendment provided that a childhood vaccination “must be ordered and administered according to ACIP’s standard immunization schedule,” it meant that, to be a “qualified person” under 42 U.S.C. § 247d-6d(i)(8)(B),

¹ See Fourth Amendment to the Secretary’s PREP Act Declaration, 85 Fed. Reg. 79,190, 79,195 (Dec. 9, 2020); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID-19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at <https://www.hhs.gov/sites/default/files/licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf>; Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID-19 Vaccines, and COVID-19 Testing, OASH, Oct. 20, 2020, available at <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>; Guidance for National Guard Personnel Regarding COVID-19 Vaccines and Immunity under the PREP Act, Dec. 18, 2020, available at <https://www.hhs.gov/about/news/2020/12/18/guidance-for-national-guard-personnel-regarding-covid-19-vaccines-immunity-under-prep-act.html> (collectively, “PREP Act Authorizations”).

² The analysis herein is specifically limited to the phrase “must be ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s),” as used in the PREP Act Authorizations. It does not bear on the interpretation of the phrase “Authority Having Jurisdiction.”

³ 85 Fed. Reg. 52,136, 52,140 (Aug. 24, 2020).

⁴ See <https://www.cdc.gov/vaccines/schedules/hcp/index.html>.

pharmacists and pharmacy interns could only order or administer a vaccine that ACIP had recommended, and only to individuals in the age groups that ACIP recommended receive the vaccine.

Subsequent PREP Act Authorizations simply adopted this requirement for the COVID-19 vaccine. When these authorizations (some of which were issued well before ACIP opined on how to allocate a COVID-19 vaccine) provided that “the vaccination must be ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s),” the authorizations meant that only COVID-19 vaccines that ACIP had recommended for use should be administered.⁵

In its longstanding routine general vaccination recommendation role, ACIP on December 12, 2020 voted in favor of recommending amendment of the *Recommended Child and Adolescent Immunization Schedule, United States, 2021* and *Recommended Adult Immunization Schedule, United States, 2021* to include COVID-19 vaccines. In addition, on December 12, 2020 and December 19, 2020 ACIP voted to specifically recommend administration in the United States of Pfizer-BioNTech’s COVID-19 vaccine (for persons age 16 years and older) and Moderna’s COVID-19 vaccine (for persons aged 18 years and older), respectively.⁶ The PREP Act Authorizations’ reference to ACIP’s recommendations is to those recommendations.

Given the anticipated limited availability of COVID-19 vaccine doses at the beginning of the vaccination program, CDC also sought ACIP’s insights on allocation for administering those limited doses. Those ACIP allocation recommendations are not relevant to the determination of whether, under the PREP Act Authorizations, a vaccination was “ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s).”

Therefore, any person who orders or administers the Pfizer-BioNTech COVID-19 vaccine to individuals age 16 or older or the Moderna COVID-19 vaccine to individuals age 18 or older⁷ satisfies the PREP Act Authorizations’ requirement that the vaccination be “ordered and administered according to ACIP’s COVID-19 vaccine recommendation(s).”⁸ This is true regardless of whether the vaccine was ordered or administered to a person in a prioritized group.

⁵ The PREP Act Authorizations use the phrase “vaccine recommendation,” not “standard immunization schedule” as used in the Third Amendment, but that is only because no standard immunization schedule existed for a COVID-19 vaccine at the time of most of the authorizations.

⁶ See https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w; https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w.

⁷ If ACIP subsequently recommends one or both of these vaccines for use in individuals in a different age group, the PREP Act Authorization requirement would be satisfied by ordering or administering such vaccine to individuals in that different age group.

⁸ This does not bear on whether the person satisfies the other requirements for PREP Act coverage.

II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.⁹ It is not a final agency action or a final order.

Persons seeking PREP Act immunity are responsible for determining whether their products are covered countermeasures, whether a person or entity is a covered person, whether reasonable precautions have been taken to facilitate the safe use of covered countermeasures, and in general, whether immunity applies to them and their activities. In order to obtain PREP Act coverage, persons must meet all requirements set forth in the PREP Act and the Declaration.

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January 12, 2021

⁹ See *Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 (“The head of an executive department ... may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]”); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).